Katie Ellison Limited

HELLO BABY

Inspection report

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This report describes our judgement of the quality of care at this service. It is based on a combination of what we found when we inspected, information from our ongoing monitoring of data about services and information given to us from the provider, patients, the public and other organisations.

Ratings

Overall rating for this location	Inadequate
Are services safe?	Inadequate
Are services effective?	Inspected but not rated
Are services caring?	Requires Improvement
Are services responsive to people's needs?	Requires Improvement
Are services well-led?	Inadequate

Summary of findings

Overall summary

Our rating of this location went down. We rated it as inadequate because:

The service did not provide mandatory training in key skills. Staff did not have the appropriate level of training on how to recognise and report abuse. The service did not control infection risk well and the clinic was visibly dirty. The design, maintenance and use of facilities, premises and equipment did not always keep people safe. Staff did not always complete relevant risk assessments for each woman using the service. Staff did not always keep detailed records of women who used the service, care and procedures. The service did not have a clear process for the management of incidents. Staff were not trained in how to recognise and report incidents and near misses.

The service did not always provide staff with access to the most up-to-date best practice guidelines and managers did not check to make sure staff followed guidance. The service did not collect any outcome data or monitor the effectiveness of care. The service did not make sure staff were competent for their roles. Staff did not always give women who used the service practical support and advice to lead healthier lives. Staff did not receive training in how to support women to make informed decisions about their care and did not always understand how to appropriately gain women's consent for their care and treatment.

Staff did not always respect the privacy and dignity of service users. Staff were not trained on how to provide emotional support to women who were distressed. Staff did not always support women, families and carers to understand their condition and make decisions about their care and treatment.

The service was not always inclusive and did not always take account of women using the service individual needs and preferences. Reasonable adjustments were not always made to help women access services. Lessons learnt from complaints were not always identified and actions were not always taken to prevent similar complaints happening.

Leaders did not always demonstrate that they had the skills and abilities to run the service. Leaders did not operate effective governance processes. Staff were not always clear about their roles and accountabilities. Leaders and staff did not always discuss and learn from the performance of the service. Leaders did not always have systems to manage performance effectively. They did not always identify and escalate relevant risks and issues and identify actions to reduce their impact. Active engagement with staff, service users and external stakeholders and organisations to plan and manage services was limited. We saw no examples of continuous learning and improvement of the service.

However:

The service had enough staff to provide care.

Staff treated women with compassion and kindness, and we observed friendly and caring interactions between staff and women.

People could access the service when they needed to

Staff felt respected, supported and valued.

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic and screening services	Inadequate 	

Summary of findings

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Summary of this inspection

Background to HELLO BABY

Hello Baby is operated by Katie Ellison Limited. Hello Baby registered with the Care Quality Commission in 2017. The service has had a registered manager in place since initial registration.

The service provides a range of ultrasound scans in 2D, 3D and 4D during pregnancy for women aged 16 years and over. It is registered to provide the regulated activity of diagnostic and screening procedures.

All scans were performed by the registered manager and the service employed five receptionists.

We carried out a monitoring call with the service on 4 February 2022. Information gathered during this call prompted the need for us to inspect the service and was considered as part of the inspection process.

How we carried out this inspection

Our inspection was announced at short notice to enable us to observe routine activity. We inspected this service using our comprehensive inspection methodology. Two inspectors carried out the inspection on 3 March 2022 with off-site support from an inspection manager and head of hospital inspection.

On the day of the inspection, we spoke with two members of staff and the registered manager.

You can find information about how we carry out our inspections on our website: https://www.cqc.org.uk/what-we-do/how-we-do-our-job/what-we-do-inspection.

Areas for improvement

Action the service MUST take is necessary to comply with its legal obligations to meet the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. Action a service SHOULD take is because it was not doing something required by a regulation but it would be disproportionate to find a breach of the regulation overall, to prevent it failing to comply with legal requirements in future, or to improve services.

Action the service MUST take to improve:

- The provider must maintain the privacy and dignity of women whilst they are using the service (Regulation 10)
- The provider must ensure infection prevention and control procedures are aligned to current best practice guidelines to prevent women being exposed to unnecessary risk. (Regulation 12)
- The provider must ensure that they assess and mitigate the risk to the health and safety of people who use the service. (Regulation 12).
- The provider must ensure the premises and equipment used for providing care are safe for use. (Regulation 12)
- The provider must ensure staff have the required level of training or skills to enable them to recognise the potential risk and protect vulnerable adults and children from abuse. (Regulation 12)
- The provider must have processes in place to ensure that staff are suitably qualified, competent, skilled and experienced to provide a safe service. (Regulation 12)
- The provider must ensure that actions are taken to prevent similar complaints happening. (Regulation 16)

Summary of this inspection

- The provider must ensure that employment checks are carried out in line with the requirements of Schedule 3 of The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. (Regulation 17)
- The provider must have effective governance processes to ensure they are able to assess, monitor and improve the quality and safety of the service. (Regulation 17)
- The provider must always have oversight of risks and challenges which could cause potential harm to women who use the service or disrupt the provision of the service. (Regulation 17)

Action the service SHOULD take to improve:

- The provider should maintain accurate and complete records of the care and treatment provided to each service user and of decisions taken in relation to their care.
- The provider should do everything reasonably practicable to make sure that people who use the service receive person centred care that is appropriate, meets their needs and reflects their personal preferences.

Our inspection findings showed that patients were at immediate risk of harm. Therefore, we urgently suspended the service to allow the provider to act on our findings. We also issued the provider with two requirement notices with actions they must complete that affected Hello Baby.

We are placing the service into special measures. Services placed in special measures will be inspected again within six months. If insufficient improvements have been made such that there remains a rating of inadequate overall or for any key question or core service, we will take action in line with our enforcement procedures to begin the process of preventing the provider from operating the service. This will lead to cancelling their registration or to varying the terms of their registration within six months if they do not improve. The service will be kept under review and, if needed, could be escalated to urgent enforcement action. Where necessary another inspection will be conducted within a further six months, and if there is not enough improvement, we will move to close the service by adopting our proposal to vary the provider's registration to remove this location or cancel the provider's registration.

Our findings

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Diagnostic and screening services	Inadequate	Inspected but not rated	Requires Improvement	Requires Improvement	Inadequate	Inadequate
Overall	Inadequate	Inspected but not rated	Requires Improvement	Requires Improvement	Inadequate	Inadequate

Inadequate

Diagnostic and screening services

Safe	Inadequate
Effective	Inspected but not rated
Caring	Requires Improvement
Responsive	Requires Improvement
Well-led	Inadequate

Are Diagnostic and screening services safe?

Inadequate

Our rating of safe went down. We rated it as inadequate.

Mandatory training

The service did not provide mandatory training in key skills. This meant that staff working in the service did not have up to date training in key skills.

Staff were not provided with training in infection control, incident reporting, equality and diversity, consent, the Mental Capacity Act or fire safety.

Mandatory training was not comprehensive. The manager told us that when staff read a policy, this was considered as training.

This level of training compliance was not adequate however it was monitored by one of the receptionists. A training matrix was used to monitor compliance, but this was not effective. It did not outline each staff members training completion or when this training was due for renewal.

Staff had been trained in conflict resolution and mental health awareness. However, this training was only valid until July 2020 and had not been repeated. In addition, two members of staff had not completed this training.

All staff had completed first aid training.

Safeguarding

Staff did not have the appropriate level of training on how to recognise and report abuse.

At the time of our inspection, no staff had completed safeguarding training above level 1 in line with the recommendations of the Intercollegiate Guidelines for Safeguarding Children and Young People and Adults: Roles and Competencies for Healthcare Staff. One member of staff had not completed any safeguarding children training.

The Safeguarding Policy did not cover all aspects of potential abuse. For example, female genital mutilation, forced marriage and child sexual exploitation were not included.

Inadequate

Diagnostic and screening services

The Safeguarding Policy did not include information about how to make a referral or contact details for the local authority safeguarding team.

The service did not have a chaperone policy and staff that we spoke with did not understand the role of a chaperone. Staff told us that family members or friends would be used as chaperones which was not in line with best practice.

We observed family members acting as interpreters for service users whose first language was not English, including when gaining consent and during scans. This exposed service users to the risk of manipulation or coercion and could mask the identification of safeguarding concerns such as forced marriage.

Following our last inspection in 2019, we told the service that they must ensure that all staff receive PREVENT training. Four members of staff had completed PREVENT training in 2019 and 2020. The manager had not completed a risk assessment to determine the frequency of training for their staff in line with Home Office recommendations. In addition, two members of staff had not completed any PREVENT training.

We saw that none of the receptionists had a Disclosure and Barring Service (DBS) check. This meant the manager could not be assured that the staff were safe to work in the service.

However, we saw that the service had referred four safeguarding concerns to the local authority.

Cleanliness, infection control and hygiene

The service did not control infection risk well. Staff did not use control measures to protect women, themselves and others from infection. They did not keep equipment and the premises visibly clean.

The environment and equipment throughout the clinic were visibly dirty and dusty including the scan machine, scanning couch, light fittings, storage cupboards and the baby changing facility.

Cleaning records did not outline how cleaning should be undertaken, what should be cleaned or any cleaning frequencies. Although staff had signed to say they had cleaned, there was no record of what had been cleaned and we found that the clinic was not clean.

Consumable items were stored on the floor for example, the couch roll. This was not in line with infection prevention and control best practice guidelines.

The design of the chairs in the scan room, waiting and viewing areas did not enable them to be effectively cleaned. This is because the chairs were not impermeable to dirt and liquid.

Whilst performing scans, the manager was not following ‘bare below the elbows’ infection prevention and control best practice guidelines.

The manager told us they completed a monthly infection prevention and control inspection. However, we saw actions that had been identified on the managers inspection were not always undertaken. In addition, the audits did not identify what was being assessed, for example the cleaning schedules, and it was apparent that the audits were not effective because the clinic was not clean.

Inadequate

Diagnostic and screening services

Changing of fabric couch covers in the scanning room was not included in the infection control policy or daily cleaning procedures. The manager told us they were changed at the end of each day, but we saw that this did not happen on the day of our inspection. Staff told us they were not aware of when this was changed or washed.

The service had a policy for cleaning the ultrasound probe however this policy was not comprehensive. Some parts of the British Medical Ultrasound Society (BMUS) guidelines were attached but these were not dated so it was not clear if these were up to date. In addition, the process for cleaning the probe was not in line with the BMUS recommendations and it was not clear if manufacturer recommendations had been considered.

The service had an infection control policy dated January 2022 and a daily cleaning procedures policy dated September 2021. The policies did not reference any relevant infection prevention and control national guidelines.

There were no handwashing facilities in the scan room. We saw the manager use hand sanitiser between each scan appointment however we did not observe any staff members washing their hands. However, handwashing posters were displayed above the handwashing sink.

Screens were in place at reception and in the scan room to help prevent the spread of COVID-19, however these screens were not clean.

All staff wore face masks.

We observed women and visitors to the clinic being asked about COVID-19 symptoms and being encouraged to wear masks and sanitise their hands-on entry to the clinic. Face masks, hand sanitiser and a waste bin were available at the entry of the clinic.

Environment and equipment

The design, maintenance and use of facilities, premises and equipment did not always keep people safe.

Floor tiles in the reception area were loose and had lifted from the floor making it uneven. One of the inspectors tripped on a loose tile. This meant this was also a hazard for women using the service.

The scan machine was broken which left sharp edges and meant that it could not be cleaned effectively. We did not see that any action had been taken to get this repaired.

Cleaning products were stored in the toilet, which was accessible to people using the service, and also in the scan room. Control of Substances Hazardous to Health 2002 (COSHH) regulations set out how these products should be stored safety and securely, for example they should be stored in a locked cupboard or room. The service was not following COSHH regulation requirements.

The scanning couch was unsafe. The couch did not have brakes which meant it was unstable when women repositioned themselves. It could also not be lowered to enabled women to safely get onto the couch.

The contents of the first aid kit in the service were out of date. When we spoke with staff, they were unaware it was out of date. However, staff later told us that a new one was on order.

There was a large amount of tangled electrical cables in the storeroom which posed a fire risk.

Inadequate

Diagnostic and screening services

The door handle on the door of the scan room was not secure. There was a risk that the handle could come off. We did not see that any action had been taken to get this fixed.

The open plan design of the reception, waiting room and viewing area meant that it was difficult for women to speak to staff or view pictures in private.

Assessing and responding to patient risk

Staff did not always complete relevant risk assessments for each woman. It was not clear if staff knew what to do if there was an emergency.

Staff did not ask or record if service users had any allergies which could expose them to an unnecessary risk of harm.

The service did not have a policy for staff to follow in the event of an emergency or a woman becoming unwell. Staff were provided with basic first aid guidance, but this did not outline local escalation procedures.

The manager and staff told us there was no inclusion/exclusion criteria outlining circumstances where women could or could not access the services provided. In addition, the manager was unable to identify any high-risk patient groups.

When we asked a staff member about women who contact the clinic with symptoms, they told us that they would direct women to contact the NHS but that they would also book them in for an appointment at the clinic. This could put women at risk of not receiving the correct care.

There was no policy for rescans and no guidance available to staff about timeframes between scans. When we spoke with staff, they told us that all requested appointments were booked unless there was no availability.

The service did not have a policy for managing women who did not attend for their appointment. Staff told us that there was no follow up process for any potentially vulnerable women who did not attend.

However, the terms and conditions outlined on the services consent form and information available on the service website recommended service users to continue to attend NHS appointments and scans.

Staffing

The service had enough staff to provide care and managers were able to adapt the clinic times according to the availability of the ultrasound technician.

The manager told us that locum staff were not used and when the ultrasound technician was unavailable, the clinic would close.

The receptionist was also responsible for supporting women to view their scan images and prepare products such as gender reveal balloons and toy bears. When this was required, the reception would be left without staff.

Records

Staff did not always keep detailed records of women's care and procedures. Records were stored securely and easily available to all staff providing care.

Inadequate

Diagnostic and screening services

The ultrasound technician did not make any record of the discussions that she had with women or scan findings. Therefore, when women returned for subsequent scans, the ultrasound technician did not have access to all relevant information to conduct a safe and effective scan.

We were told that in the event of abnormal findings, these would be recorded on the bottom of the consent form. However, we did not see this being used.

Scan images were stored electronically for 20 weeks. Consent forms were in paper form. Completed consent forms were stored in a lockable filing cabinet for one month and then moved to offsite secure storage.

Incidents

The service did not have a clear process for the management of incidents. Staff were not trained in how to recognise and report incidents and near misses.

The service did not provide training for staff on how to recognise and report an incident.

The manager told us that no incidents had been reported since the clinic opened.

The service had a duty of candour policy however this was not fit for purpose. It did not outline how duty of candour should be applied when things went wrong. In addition, when we asked the manager, they did not demonstrate that they understood or knew when they should apply duty of candour.

The service had an accident procedure; however, this did not state that staff should take any action other than filling out an incident report form. This procedure was not dated.

There was a separate incident/accident reporting policy dated June 2021 which stated that the only action staff should take was to report the incident to the owner.

There was a further accident/incident reporting policy, also dated June 2021. This was a more comprehensive policy. This policy stated that staff should report incidents to their supervisor, the human resources department and through an online system. However, the service did not have a human resources department or online reporting system.

Are Diagnostic and screening services effective?

Inspected but not rated

We did not rate effective. We found:

Evidence-based care and treatment

The service did not always provide staff with access to the most up-to-date best practice guidelines. Managers did not check to make sure staff followed guidance.

The British Medical Ultrasound Society Guidelines for Professional Ultrasound Practice displayed in the clinic were dated December 2020. The national guidelines had been updated in December

2021. In addition, policies that we looked at, for example the infection control and safeguarding policies, did not reference evidence based best practice guidance and did not all have review dates. This meant that staff may not be following the most up to date guidance.

The manager did not perform any audit activity other than a monthly infection prevention and control inspection in order to monitor the quality and safety of the service. The manager could not evidence how they were assured that staff were working in line with evidence based best practice guidelines.

Patient outcomes

The service did not collect any outcome data or monitor the effectiveness of care.

We spoke with the manager about monitoring of outcomes. There were no service level targets or performance indicators. Scan times, waiting times and outcome rates were not reviewed to monitor the effectiveness of the service.

The manager told us they kept a record of any gender inaccuracy reports. However, they were unable to tell us how this information was used to improve the service.

Competent staff

The service did not make sure staff were competent for their roles.

The manager of the service was also the ultrasound technician who performed all the scans. They had completed some training in 2014 and 2015 to perform scans in 2D, 2D and 4D. They had no further training or competency checks since 2015.

The service had an induction plan for new staff. However, this did not outline what competencies or training staff would need before they could work independently.

We asked to see the completed induction document for the most recently employed member of staff. We were sent a document which was created after the day of our inspection. This document included information about some recruitment checks but did not outline what induction the staff member had been given or how competence and confidence had been assessed prior to them working independently.

We reviewed personnel files for all staff. Not all staff had employment references and not all staff had received a Disclosure and Barring Service (DBS) check. In addition, no staff had completed health declarations to ensure that, after reasonable adjustments, they were able to able to properly and safely perform their role. This meant staff were not employed in line with schedule 3 of the Health and Social Care Act 2008.

Reception staff received appraisals every six months with the manager. The appraisal was a structured process which included performance and development.

Multidisciplinary working

Staff worked together but did not always work with other stakeholders to benefit women.

The manager told us that she had no access to other ultrasound technicians and that no peer review took place. If an abnormality was found, the women would be advised to contact the local hospital. The manager would only contact the hospital in urgent circumstances.

Staff told us that they had a closed message group where they could keep in contact with each other and share relevant information.

Team meetings were held every six months however these meetings did not have a formal structure.

Seven-day services

Services were available five days each week. However, the service occasionally opened on a sixth day if required.

This service does not provide emergency care and treatment.

The clinic was open for scans Tuesday to Saturday, and occasionally on a Sunday. Although no women would be booked in for a scan on a Monday, the reception was manned to allow patients to call and book an appointment.

Health promotion

Staff did not always give women practical support and advice to lead healthier lives.

There was no information on display in the clinic to promote healthy lifestyles. patients.

The service did not collect any lifestyle information from women in order to offer advice in line with national priorities for health such as smoking and alcohol and drug dependency.

The service website included information about the benefits of exercise during pregnancy and things women should avoid for a safe and healthy pregnancy which included smoking.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

Staff did not receive training in how to support women to make informed decisions about their care. They did not always understand how to appropriately gain women's consent.

Staff did not receive training in consent, the Mental Capacity Act or Deprivation of Liberty Safeguards. When we spoke with the manager about this, they were unable to differentiate between the Mental Health Act and the Mental Capacity Act.

The service had a consent policy dated April 2021. However, the policy did not outline what process staff should take to gain consent.

We saw that family members acted as interpreters when consent was gained. Staff told us that this was normal practice. This puts women at risk of coercion or manipulation and is not in line with best practice guidelines.

The service did not monitor that service user consent was taken in line with legal requirements. The manager could not provide evidence of how they were assured that this was done correctly.

We reviewed 18 consent forms and found that these were not always fully completed. Three forms had no due date or last menstrual period, ten did not include the name of the services users NHS midwife and two did not have the GP name recorded.

Inadequate

Diagnostic and screening services

The service did not have a policy or any guidance for staff to follow for managing women experiencing acute anxiety or mental health crisis.

Are Diagnostic and screening services caring?

Requires Improvement

Our rating of caring went down. We rated it as requires improvement.

Compassionate care

Staff treated women with compassion and kindness but did not always respect their privacy and dignity.

Women were not able to talk to staff at reception without being overheard by other people in the waiting room. There was no signage to explain that women could ask to speak with staff privately. If women asked to speak with staff in private, this could only happen in the scan room due to the layout of the clinic.

The service was not able to ensure the privacy of the service users. We observed consent being taken in the reception area. Scans were booked at 15-minute intervals which did not allow any time between scans if people needed it.

People in the waiting room could hear the heartbeat of the foetus of the woman being scanned. There was a risk that conversations in the scan room could be overheard in the waiting room.

We also observed service users being asked to wait in the viewing area whilst other service users were viewing their scan pictures.

The service had a confidentiality policy dated January 2022. However, this policy did not outline what actions staff should take to maintain the privacy of women who used the service.

We observed six scans during our inspection and saw staff treated women with kindness and respect.

Many of the women we saw during our inspection were having gender reveal celebrations so had chosen not to find out the gender at the time of the scan. We saw that staff supported this decision and worked to ensure that the gender was not revealed.

Emotional support

We observed friendly, kind and caring interactions between staff and women. However, staff were not trained on how to provide emotional support to women to minimise their distress.

The service did not have a separate area which could be used for women who were upset or distressed. The manager told us that the scan room would be used if this happened, but this would then cause delays for other people using the service.

Staff told us that they do not have any options for signposting women to support services other than NHS maternity services.

Inadequate

Diagnostic and screening services

The manager told us that they would try to contact women within a few days of their appointment if they had received bad news or had been advised to contact their NHS midwife. However, there was no policy in place for this process and the manager told us that this did not always happen.

Staff were not trained on how to provide emotional support to women or in breaking bad news to minimise their distress.

Understanding and involvement of women and those close to them

Staff did not always support women, families and carers to understand their condition and make decisions about their care and treatment.

We saw that the service had received a complaint in December 2021 from a woman who complained about not being supported when she felt anxious during her scan. There was also a complaint theme of women feeling rushed during their appointment. This was the same complaint theme that we saw at out last inspection in 2019.

The service offered various scan packages and this information was displayed in the clinic and on the website so that women could choose which package they wanted.

Women who used the service were able to bring along friends and family members, including children, to their scan. During our inspection, we observed staff making everyone feel welcome in the scan experience, including family members and friends.

Women and their families could give feedback on the service. The complaints policy was on display in the clinic and we saw staff encouraging women to leave reviews on social media.

Are Diagnostic and screening services responsive?

Requires Improvement

Our rating of responsive stayed the same. We rated it as requires improvement.

Service delivery to meet the needs of local people

The service planned and provided care in a way that met the needs of local people and the communities served.

The service offered scan appointments at evening and weekends to accommodate the needs of people who worked Monday to Friday.

The clinic was easily accessible by public transport and there was free parking available on nearby streets.

Meeting people's individual needs

The service was not always inclusive and did not always take account of women's individual needs and preferences. Reasonable adjustments were not always made to help women access services.

Inadequate

Diagnostic and screening services

During our call with the manager on 4 February 2022, we were told that additional needs were not discussed or considered at the time of booking. The manager told us that accessibility information was included on the website however we were not able to find any information about this on the service website.

The service did not have a policy for equality, diversity and inclusion.

Staff did not receive training in equality, diversity and inclusion and not all staff were aware of protected characteristics and their responsibilities in line with the Equality Act 2010.

The service did not have a policy which outlined how the service adapts to and meets the needs of those with mental health needs or learning disabilities.

The service had a language policy dated January 2022 which stated that staff could access translation services if an interpreter was needed. However, the manager and staff told us that when required, women were encouraged to bring a friend or family member who would act as an interpreter. This could put vulnerable women at risk.

The service did not have facilities to meet the needs of people with sight or hearing problems. There was not a hearing loop and no information available in accessible formats.

The doorways in the clinic were wide enough to accommodate a wheelchair, however the waiting room and patient toilet were small, and it may have been challenging for a wheelchair user to safely use the facilities.

The couch in the scan room was not adjustable. A step was provided to enable women to get onto the couch. However, we saw a woman with back issues who was using crutches struggle to get on the couch and who would have benefited from the couch being lower.

Staff had received training in mental health awareness however this training had expired in July 2020 and there were no plans for this training to be repeated

Access and flow

People could access the service when they needed it.

Women could access an appointment booking system online which generated an automated booking confirmation. Appointments could also be booked in person or by telephone.

Staff told us that the appointment booking system worked well.

The manager worked to keep the number of cancelled appointments to a minimum. The service kept a log of appointments which had been cancelled for non-clinical reasons.

Learning from complaints and concerns

Lessons learnt were not always identified and action was not always taken to prevent similar complaints happening. However, it was easy for people to give feedback and raise concerns about care received. The service responded to concerns and complaints seriously.

Inadequate

Diagnostic and screening services

Following our last inspection, we told the provider they must ensure that actions are taken to prevent similar complaints happening again. At this inspection, we found that the theme of complaints was the same as was found at the previous inspection about service users feeling rushed. Other than offering a free scan, no actions had been taken to address this complaints theme.

The service had a complaints policy dated June 2021. This policy stated that complaints were reviewed every three months to identify emerging patterns. Although we saw that complaints were discussed in team meetings, we did not see that themes had been identified or acted upon.

Staff did not receive training in how to respond to a complaint, however the complaints policy included a standard response which staff could use to acknowledge complaints and that explained what would happen next.

The service clearly displayed information about how to raise a concern in patient areas. The complaints process was on display in the waiting area and was included on the bottom of the consent form.

Are Diagnostic and screening services well-led?

Inadequate

Our rating of well-led went down. We rated it as inadequate.

Leadership

Leaders did not demonstrate that they had the skills and abilities to run the service.

The manager did not understand the challenges to safety, quality and sustainability and had not always identified actions to address them.

The manager did not show that they understood their role in keeping people safe and in meeting the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

The manager did not demonstrate that they understood the importance of staff having the skills and knowledge to carry out their roles safely and effectively.

However, staff told us the manager was supportive, visible and approachable. Throughout the inspection, we saw the manager speaking with and supporting staff and women using the service.

Vision and Strategy

The service did not have a formally documented vision for what it wanted to achieve and a strategy to turn it into action. The manager and staff did not always understand how to apply them or monitor progress.

The manager told us that they wanted to provide service users with a safe, caring and comfortable environment. They wanted to deliver 2D and 4D live ultrasound technology to all customers in a professional manner and that they wanted to promote excellence and ensure accuracy in all areas of scanning.

Inadequate

Diagnostic and screening services

The vision and strategy and vision had not been formalised or shared with staff. Staff that we spoke with did not know if the service had a vision or strategy.

There were no systems in place for the manager to measure the service against this vision other than service user feedback.

Culture

Staff felt respected, supported and valued. They were focused on the needs of women receiving care. The service had an open culture where women, their families and staff could raise concerns without fear.

Staff told us that they felt respected and valued and that they were happy in their roles.

The manager and staff spoke passionately about the service and the care they provided for women.

Staff told us that they felt supported by the manager and they felt able to raise any concerns that they may have.

We witnessed staff interacting well with each other.

The service had a whistleblowing policy dated April 2021.

Governance

The manager did not operate effective governance processes. Staff were not always clear about their roles and accountabilities. Staff met every six months, but they did not always discuss and learn from the performance of the service.

The service governance processes did not support the safe and effective delivery of care. The manager had limited oversight of the concerns that we identified during the inspection.

Following our inspection in 2019, we told the provider they should consider adding review dates to their policies and procedures. At this inspection we reviewed 12 policies and found that these did not contain review dates. In addition, some policies were not fit for purpose, for example the duty of candour policy did not contain guidance about what to do if an incident occurs or the need to apologise when things go wrong.

Following our last inspection, we told the provider that they should consider reviewing the cleaning procedures. At this inspection, we found that cleaning schedules were not fit for purpose and the clinic was not clean. The process for checking the cleaning of the clinic was not structured. We saw the manager completed an inspection each month, but issues identified had not been acted upon. In addition, the clinic was not clean.

The service had multiple policies for the same topic. For example, they had a cleaning procedures policy, an infection control policy and a probe cleaning policy. This meant staff did not have access to a single effective policy to support them in their roles. Staff we spoke with told us that they felt there were too many policies. Policies did not include review dates, and it was not clear how often the manager was reviewing and updating policies.

Processes to ensure that staff were suitably qualified, competent, skilled and experienced persons to ensure provision of a safe service were inadequate. For example, the manager had not obtained DBS checks for all staff.

Inadequate

Diagnostic and screening services

The service did not have criteria in place which specified which service users could access the service safely. We asked staff what criteria they would use when booking an appointment. Staff told us that they would book anyone in for an appointment if there was availability. In addition, when we spoke with the manager on 4 February 2022, they were unable to identify any service users who would be excluded because they would be considered high risk.

The manager had not acted upon any of the areas for improvement that were identified in our last inspection report in 2019. Although the manager told us they had created an action plan, they were unable to find this at the time of our inspection. Following our inspection, we were provided with an action plan, but we found this had been created after our inspection in March 2022. In addition, we saw that some of the issues identified in our inspection in 2019 were still not resolved. For example, in 2019 we told the provider:

- they must ensure that staff have the appropriate training to ensure that they understand the principles of the Mental Capacity Act in relation to obtaining valid consent. At this inspection we found that consent forms were not always fully completed and that family members were being used to translate consent forms.
- they must ensure that all staff receive sufficient safeguarding training. At this inspection, we found that no staff had been trained above level one for safeguarding training which is not in line with the intercollegiate safeguarding recommendations.

The client referral process had been read and signed by staff in April and June 2021, however the staff member who created this policy told us that the manager had not yet read and agreed the process.

Team meetings were held every six months however these meetings did not have a formal structure and the performance of the service was not discussed.

The manager kept a record of all policies which had been split across the year for when they should be reviewed and read by staff.

Women could book into the clinic for a blood test to find out the gender of their baby. This service was offered by another provider who provided the equipment and staff and performed the blood test. Hello Baby, provided the clinic space, booked the appointments and posted the samples to the laboratory. There was a service level agreement in place which outlined clear responsibilities for each service.

Management of risk, issues and performance

The manager did not have systems to manage performance effectively. They did not identify and escalate relevant risks and issues and identify actions to reduce their impact. They did not have clear plans to cope with unexpected events.

It was highlighted in our last inspection report that the provider did not ensure that it did everything reasonably practicable to mitigate any risks to those using the service. At this inspection we saw that the risk register was not fit for purpose. The risks identified did not meet the definition of a risk. However, in addition these were not rated or graded in terms of impact or likelihood. Appropriate mitigations and reviews were not documented.

A fire risk assessment by a suitably competent person is a legal requirement. This was not in place and we identified a potential fire risk in the clinic. Staff had not received any training in fire safety. However, fire extinguishers in the clinic has been recently tested.

Inadequate

Diagnostic and screening services

Staff in the service regularly worked alone. There was no lone worker policy, lone working had not been identified as a risk and therefore this was also not on the risk register. When we discussed this with the manager, they did not understand why this was required. This should be in place to keep staff safe.

The service had a business continuity plan which did have a review date. This was out of date as it had been due for review in 2018. However, it was still in the policy folder which staff used.

The service had a major incident continuity policy which was dated June 2021. This policy outlined an assembly point but did not outline the responsibilities of staff in an incident and how information would be assessed in a power outage.

Information Management

The service did not collect reliable data and analyse it. Staff did not always have access to the data they needed, in easily accessible formats, to understand performance, make decisions and improvements. However, the information systems were secure.

The service did not collect or analyse any performance data, such as rescan rates and gender accuracy data.

Staff did not receive any training in information governance.

The service had a data protection and confidentiality policy which stated that scan images were destroyed after 20 weeks and consent forms after 12 months. The manager kept a log of the weekly destruction of client files.

Information about retention of scan images was included in the terms and conditions.

Staff appraisals were also stored in the folder with the policies which was accessed by all staff.

Completed consent forms stored in a locked filing cabinet in storeroom. Then moved into a secure garage which was separate to the clinic.

Engagement

Active engagement with staff, service users and external stakeholders and organisations to plan and manage services was limited.

During our call on 4 February 2022, the manager told us that they had a patient survey that was handed out to service users each month. When we asked for the results of this survey, we were told that this has not been completed since 2020. The manager shared a blank copy of the survey with us; however, this document had been created after our inspection in March 2022.

The manager told us that customer satisfaction was measured using social media reviews. However, they were unable to tell us how this information was used and what changes had been made to improve the service.

The manager had a list of contact numbers for the local early pregnancy units, but no contact had been made with these services, and when referrals had been made, no feedback had been sought.

Staff appraisals included a section for staff to provide ideas and feedback. However, we did not see evidence of how this feedback was used to make changes or improve the service.

Inadequate

Diagnostic and screening services

The manager had liaised with the local domestic abuse team who had provided posters and pocket guides which we saw displayed in the clinic.

Learning, continuous improvement and innovation

We saw no examples of continuous learning and improvement of the service.

Staff and managers did not undertake training in quality improvement therefore, the opportunity to identify areas for improvement was limited.

Performance data was not collected and made available to staff to enable them to change or improve practice.

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

The table below shows the legal requirements that were not being met. The provider must send CQC a report that says what action they are going to take to meet these requirements.

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 10 HSCA (RA) Regulations 2014 Dignity and respect The provider did not maintain the privacy and dignity of women whilst they were using the service.

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 16 HSCA (RA) Regulations 2014 Receiving and acting on complaints • The provider did not ensure that actions were taken to prevent similar complaints happening.

This section is primarily information for the provider

Enforcement actions

Action we have told the provider to take

The table below shows the legal requirements that were not being met. The provider must send CQC a report that says what action they are going to take to meet these requirements.

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment The provider did not ensure infection prevention and control procedures were aligned to current best practice guidelines to prevent women being exposed to unnecessary risk. The provider did not assess and mitigate the risk to the health and safety of people who use the service. The provider did not ensure the premises and equipment used for providing care are safe for use. The provider did not ensure staff had the required level of training or skills to enable them to recognise the potential risk and protect vulnerable adults and children from abuse. The provider did not have processes in place to ensure that staff were suitably qualified, competent, skilled and experienced to provide a safe service.

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 17 HSCA (RA) Regulations 2014 Good governance The provider did not carry out employment checks in line with the requirements of Schedule 3 of The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. The provider did not have effective governance processes to ensure they were able to assess, monitor and improve the quality and safety of the service.

This section is primarily information for the provider

Enforcement actions

The provider did not always have oversight of risks and challenges which could cause potential harm to women who use the service or disrupt the provision of the service.